ATTACHMENT 3

AGREEMENT STATES COMMENT LETTERS

From: "Johns, George" <GJOHNS@health.state.ia.us>
To: "'lmp1@nrc.gov'" <lmp1@nrc.gov>
Date: 8/8/02 12:29PM
Subject: Iowa's response to Draft Options Paper on Part 35 Training and Experience

The Chief of Iowa's Bureau of Radiological Health has reviewed the following and requested that it be forwarded to you.

The current rule requires 200 hours of classroom training, 500 hours of supervised clinical experience and 500 hours of supervised work experience for use of radiopharmaceuticals in imaging and localization studies. The new rule states that a physician must only have 750 hours and is non-specific. Based on the Draft Options Paper, it would appear that the board certifications do not even meet the reduced standards, which take effect October 24, 2002. In other words, despite a 500-hour reduction in the training and experience requirements, only the Certification Board of Nuclear Cardiology meets the new NRC standards.

If the board certification process includes testing, which effectively evaluates a physician's didactic and clinical knowledge, IDPH would normally have little problem accepting that certification. However, because the regulatory community is tasked with promulgating rules to protect the health and safety of the patient, the staff, and the physician, the question that arises is: How much training can be avoided without compromising health and safety?

It seems odd that a certifying body would not be interested in establishing consistent training and experience standards. IDPH does not agree that the standards should be altered to accommodate the boards.

The certification process, if properly designed, can be used to determine competency. However, when considering training for non-board certified physicians, the difficulty that arises is determining how much training and experience should be required in lieu of a board certification. I believe that the primary objection expressed by many other Agreement States is that the NRC appears to be proposing a lesser training and experience standard for physicians with a board certification. Again, the standard has already been diminished. At what point does the NRC wish to say that the level of training is too little? It would appear that the NRC believes that the certification boards are capable of making that decision. It is Iowa's opinion that the NRC should not abdicate its responsibility.

In summary, the NRC has determined that regulations pertaining to training

and experience are a Compatibility B. The final rule has already reduced the training and experience requirements to a level that many believe to be compromising health and safety. The standard should not be further compromised. Therefore, the certifying boards, which have inconsistent standards among themselves, should be held to the new standards. Board certified and non-certified physicians should meet those same standards. Finally, if Agreement States are required to be consistent with the NRC, IDPH believes that the training and experience for physicians should be also consistent.

From: "Frazee, Terry" <Terry.Frazee@DOH.WA.GOV>
To: "'LMP1@nrc.gov'" <LMP1@nrc.gov>
Date: 8/27/02 1:28PM
Subject: STP-02-061 -- Comments on Part 35 T&E

I have reviewed the Draft Options Paper presented on the Technical Conference Forum and have the following comments:

The ACMUI request is proof of what the Agreement States have known for a long time -- "Authorized Users" are clinicians (or "authorized prescribers", if you will) and, for the most part, NOT "users" or "handlers" of radioactive material; and obviously the Board process reflects that. The new T&E regulations (Option 1) are written as minimum requirements for the "use" or handling of radioactive material, i.e., with radiation safety in mind, and should be maintained "as is". An eleventh hour realization that the "clinical practice" Boards are "just that" does not negate the value of the T&E requirements geared to radiation safety!

Bottom line: The training and experience requirements represent the MINIMUM radiation safety requirements applicable to ALL "users" (even Board certified individuals) and should be kept for ALL. We don't "buy" the shortage argument. The Boards have two years to show how they meet (or will meet) or exceed the minimum requirements. Even if the ACMUI (rather than NRC staff) is used to "approve" Boards, the standard should be the same. Professional judgment can be used, BUT the STANDARD remains the same. The concern that "candidates seeking authorized user status may bypass the board certification pathway and select the simpler T&E process" is more reflective of Board concern for losing its candidates than for diminution of radiation safety. Our concern as regulators should be that the individuals we approve as "authorized users" are adequately trained with sufficient experience to handle the radioactive materials safely. Our first responsibility is to "do it right", not just pick the "easy way".

Therefore:

1. Leave the basic T&E alone. A lot of time and effort has been expended getting the "minimum" radiation safety standard to this point. "Last minute" changes are suspect.

2. Modify the certification (preceptor) requirement as recommended by ACMUI. This makes sense for Board certifications and further makes it clear that radiation safety rather than clinical skills are the focus of the regulatory requirement.

3. Set specific training requirements for new devices or modalities that can build upon the basic requirements for existing modalities. Existing authorized users should already have the basic radiation safety training and

experience and need only specific training for the new device or modality.

4. Publish "Approved Boards" on the web site (and not in regulation) for ease and convenience of all concerned.

If there are any lessons to be learned here, one is: "license the techs" and leave the physicians to their Boards (with ACMUI setting the bar for "authorized prescribers"); and the other is: last minute jockeying to change the "standard" means the rule may not be "perfect" and therefore "casting it in concrete" (compatibility B) may be premature!

Note to Agreement States: comments are due by August 30!

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"The Department of Health works to protect and improve the health of people in Washington State"
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This message from Terry C. Frazee
e-mail terry.frazee@doh.wa.gov

Quick ways to reach me:
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Also, visit our Home Page at
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September 11, 2002

U.S. Nuclear Regulatory Commission
ATTN: Linda M. Psyk, NMSS
Mail Stop TWFN 8-F-5
Washington, D.C. 20555

Re: Draft Options Paper, Part 35 - Training and Experience Requirements (STP-02-061)

Dear Ms. Psyk:

The Illinois Department of Nuclear Safety hereby submits the following comments on the above-identified draft options paper. The paper describes a recommendation by the NRC's Advisory Committee for Medical Use of Isotopes (ACMUI). The recommendation suggests a basis for the NRC to recognize training approved by professional specialty boards and provides an alternative training and experience pathway for individuals without board certification. It also proposes training and experience requirements for those working with remote afterloaders and gamma stereotactic radiosurgery units. The options paper concludes that the NRC should accept the advisory committee's recommendation.

Except for misgivings about the ACMUI's idea for the preceptor concept, the Department of Nuclear Safety does not object to either the advisory committee's recommendation or the NRC's plan to list recognized specialty boards on its website instead of in Part 35. We believe that with one additional change, the ACMUI's recommendation would provide effective training and experience requirements. We also have suggestions that would clarify the NRC's expectations for training of individuals working with future technologies.

The Preceptor Concept. We strongly oppose the idea of reducing the amount of assurance required of a preceptor when vouching for an individual seeking authorized status on a medical use license. The revision of Part 35 that will go into effect on October 24, 2002, requires a preceptor to verify that the individual is competent to

perform independently the duties required by a medical use license. The Department of Nuclear Safety believes that this principle must be preserved if the revision is to be effective over time.

The ACMUI recommends two traming and experience pathways leading to authorized status on a license. The more common track is certification by a professional specialty board. The Department of Nuclear Safety supports the ACMUI's vision of how this should be done. We believe that the board certification process contains prerequisites, inherent milestones, and internal certifications that are predictive of effective performance by board-certified individuals. We expect these individuals typically to be competent in the duties required by a medical use license.

The alternative training and experience pathway provides a method other than board certification for an individual to achieve authorized status on a medical use license. It allows the individual to acquire training and experience and then furnish a preceptor statement asserting that he or she is prepared to effectively perform the duties required by a license. Although this is a valid process overall, we strongly oppose the ACMUI's idea of reducing the assurance that would be required of a preceptor. Instead of an attestation of competency, the ACMUI wants the NRC to require only verification that training was completed. Thus, the NRC is asked to accept less assurance of competency from the alternative pathway than through board certification.

The NRC removed many prescriptive requirements from the revision of Part 35, in part because of assurances that the regulated community would assume increased responsibility for the performance of its members. Indeed, when the revision was being drafted, the ACMUI was not opposed to preceptors appraising the competence of individuals seeking authorized status on medical use licenses. We believe that the ACMUI recognized the need for increased self-regulation if Part 35 were to become more performance-based.

In the interim, however, it appears that a misunderstanding has arisen between the ACMUI and the NRC. We believe that the wording of the revision of Part 35 has led the ACMUI to conclude that the NRC is seeking a guarantee of clinical competency. Instead of such a broad guarantee, we believe that the NRC actually requires only an *opinion* about the ability of an individual to independently perform the *duties required by a license.* This opinion would not require the preceptor to vouch for the individual's overall clinical competency.

We believe that the positions of both the NRC and the regulated community would be served if this nuance were clarified. Here is a suggestion to modify the several requirements for preceptor statements in Part 35:

> Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraph_____ of this section. The written statement shall be signed by a preceptor_____ who meets the requirements in _____ or equivalent Agreement State requirements, and shall include verification that, to the preceptor's best knowledge, the individual is competent to function independently as an_____ for-the medical uses authorized under_____ .

Future Technologies. The ACMUI's recommendation includes a training requirement for remote afterloaders and gamma stereotactic radiosurgery units. The recommendation would require modality-specific training in device operation, safety procedures, and clinical use. The Department of Nuclear Safety supports this recommendation.

Besides the training requirements for the above modalities, however, we suggest that the NRC also identify its training expectations for future technologies. Here is a clarification to subsection 35.12(d) of Part 35 that we believe would accomplish this:

> 35.12(d)(1)(iv) Specialized training beyond that described in paragraph (b)(l) of this section. A radiation safety officer, authorized user, authorized medical physicist, or authorized nuclear pharmacist for a use authorized under section 35.1000 shall have training in the use for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for the appropriate position. It may also be satisfied by receiving training supervised by a radiation safety officer, authorized user, authorized medical physicist, or authorized nuclear pharmacist, as appropriate, who is authorized for the use for which authorization is sought.

A Role for the ACMUI. The Department of Nuclear Safety believes that the ACMUI should assume an active role in establishing specific training and experience criteria for future technologies. We suggest that the NRC ask the advisory committee to recommend training specifics for each new use under section 35.1000. This recommendation should describe the training and experience qualifications necessary under paragraph (b)(l) of section 35.12. It should also specify the number of hours or cases required to satisfy the specialized training requirement suggested above [new paragraph (d)(1)(iv)]. This practice would capitalize on the advisory committee's familiarity and expertise in new technologies.

After evaluating the ACMUI's recommendation, the NRC should promptly post new training and experience requirements on its website. This would make them quickly available to the regulated community and the Agreement States, thereby standardizing requirements for new technologies as they emerge.

Thank you for the opportunity to comment on this draft options paper. My telephone number is 217-785-9930 if you have questions or comments.

Sincerely,

Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:kjg

cc: Jim Lynch
NRC Region III

Linda M. Psyk, NMSS
U.S. Nuclear Regulatory Commission
Mail Stop TWFN 8-F-5
Washington, DC 20555

Re: STP-02-061 - Part 35 - Training and Experience Requirements

Dear Ms Psyk:

This letter serves as my comment on the above referenced document. I have submitted comments to you earlier, via e-mail, regarding the ACMUI Subcommittee recommendation dated July 17, 2002.

In reading the above document, I find some inaccurate statements. The following is my response to each of these items.

1) If the draft final rule became effective 6 months after the publication date, there could be potential shortages of authorized individuals.

Response: This appears to be a key item of concern to the ACMUI. However, I fail to see the problem. During the last few years, nuclear cardiologists have not had a board certification available to them, yet there has been no shortage of nuclear cardiologists applying for, and receiving, authorized user status.

2) The ACMUI expressed concern that the boards may become "marginalized", because potential candidates seeking authorized user status may bypass the board certification pathway and select the simpler T&E process.

Response: When the NRC revised Part 35 in the 1980's, the various boards were queried as to their radiation safety requirements for board eligibility. These requirements became the basis for the optional training and experience requirements. Therefore, an individual who was not board certified, was required to be board eligible (in regards to radiation safety) in order to be approved as an authorized user. If any changes were made to the radiation safety training and experience required to sit for a board listed in Part 35, the NRC should have been made aware so they could review the possible impacts on radiation safety.

During the rule revision process, the Part 35 Working Group (of which I was a member) spent many hours with the ACMUI as well as their subcommittees for diagnostic and therapeutic uses. Many changes were made in the training and experience requirements

based on the discussions and recommendations of the members. It was made very clear that only those boards that showed they required that a board candidate meet the optional training and experience requirements would be "recognized" by the NRC, and placed on the on the NRC website list. Over and over again, between 1998 and 2000, the ACMUI membership expressed understanding and approval of the Working Group's revisions to the training and experience requirements.

Board certification should represent the best the respective field has to offer! Certification isn't for everyone. Certification should indicate that an individual has "gone the extra mile", not only to be the best they can be in their field, but to continue to strive to maintain that high level of overall competence in their chosen profession. Surely being board certified is worth more than just the ability to easily become an authorized user on a radioactive material license!

I perceive the currently listed boards did not pay attention to the revised training and experience requirements, so they are not prepared for the implementation of the new rule. I do not see this as a reason for changing the rule. I commend the Certification Board of Nuclear Cardiology for being attentive to the revised rule, and preparing for its implementation.

The following are my responses to the discussion topics.

1) Under the current Part 35, boards are not required to meet specific didactic/laboratory training and experience requirements to attain NRC recognition.

Response: As I stated above, when the training and experience requirements were revised during the 1980's, the intent was that the boards **would** meet the specified didactic/laboratory training and experience requirements to attain NRC recognition. However, this intent seems to have been forgotten over the years. The revised rule only reaffirms the old intent, leaving no doubt to a perspective board as to what radiation safety training and experience requirements they must have to attain NRC recognition.

2) Under the current rule, preceptor certification is not required for board certification. During the board certification process, the board makes its judgement that a candidate has satisfactorily completed the board's program and that the individual will be able to carry out the duties of this certification. Could another qualified

individual (e.g. a program director, a department head, or a professor) also sign the certification? In the case of the board certification process, can the members of the board collectively act as a "preceptor"?

Response: I again state that the intent of the current rule was that the boards require preceptor certification. I do not have a 1980's NRC definition for "preceptor", so I cannot say that the definition has not changed. In the revised rule, Preceptor is defined as "...an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer". Using this definition would not allow the boards to accept certification from a "qualified individual".

I believe that another individual can be allowed to sign on behalf of the actual preceptors. However, such an individual should be the preceptor's supervisor, such as a department head or program director, and a list of the preceptors should be included as reference.

I do not believe that members of the board, who have no personal knowledge of the "qualified individual", should be able to collectively act as a preceptor. I believe the "qualified individual" should be able to submit signatures of preceptors, or the preceptor's supervisor as specified in the previous paragraph, as part of their qualifications. The members of the board could decide to allow an individual to participate in any examination process without the individual submitting the necessary preceptor signatures. However, final certification should be withheld until the required preceptor signatures are submitted.

3) Board programs do not specifically include training and experience requirements for new modalities.

Response: It was the intent of the working group, in conjunction with recommendations from the ACMUI, that the training and experience requirements for other medical uses of byproduct material (emerging technologies) be handled on a case-by-case basis. No one can currently state what isotopes, chemical forms, physical forms, or routes of administration will fall into this area in the years to come. That is the reason the rule seems so vague. The intent is to make clear to the licensee what will be required of them to request licensed use of a new medical use not covered by the current rules. The example of a medical physicist with no experience in the use of

an HDR does not fall under this rule. Rather, it falls under 35.51. To try and tie down 35.1000 to something we are currently aware of has been pointed out as improper in public meetings. Specifically, the working group was using intravascular brachytherapy as an example of an emerging technology covered under this rule. Cardiologists and physicists pointed out that they do not consider intravascular brachytherapy an emerging technology. They consider it a current technology.

Existing qualified individuals wishing to use emerging technologies will have to submit information regarding the radiation safety hazards of the use to the NRC, and the NRC will then determine the necessary radiation safety training and experience requirements to become an authorized user, authorized medical physicist, etc.

Regarding the two options, my recommendation is as follows:

I believe the NRC should adopt Option 1, with two caveats. The ability of the Certification Board of Nuclear Cardiology to meet the revised requirements has proven that it can be done. However, the NRC could consider extending the old Subpart J training and experience requirements, as they are currently, until October 24, 2004. This gives the current boards another two years to meet the new requirements.

I also believe the NRC should allow the boards to accept another individual to sign on behalf of the actual preceptor, as long as the individual is the preceptor's supervisor, such as a department head or program director, and they submit a list of the preceptors as a reference.

Thank you for the opportunity to comment on this options paper. Should you have any questions, please feel free to contact me at 334-206-5391, or by e-mail at dwalter@adph.state.al.us.

Sincerely,

David Walter, Director
Radioactive Materials Licensing
Alabama Office of Radiation Control